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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,387	10/22/2003	Mark Werner	372768-341524	8628
23911	7590	08/07/2006	EXAMINER	
CROWELL & MORING LLP INTELLECTUAL PROPERTY GROUP P.O. BOX 14300 WASHINGTON, DC 20044-4300			DEVI, SARVAMANGALA J N	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 08/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/691,387	Applicant(s) WERNER ET AL.	
	Examiner S. Devi, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06/19/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) 5 and 6 ~~is/are~~ are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>032406</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election

1) Acknowledgment is made of Applicants' election filed 06/19/06, with traverse, of invention I, claims 1-4, in response to the restriction requirement mailed 05/18/06. Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (M.P.E.P § 818.03(a)).

Status of Claims

2) Claims 1-6 are pending in this application.

Claims 5 and 6 have been withdrawn from consideration as being directed to non-elected inventions. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03.

Elected claims 1-4 are under examination. An Action on the Merits for these claims is issued.

Information Disclosure Statement

3) Acknowledgment is made of Applicants' information disclosure statement filed 03/24/06. The information referred to therein has been considered and a signed copy is attached to this Office Action.

Abstract

4) The abstract of the disclosure is objected to because the number of words contained in the abstract exceeds the number of words permitted. The abstract is further objected to for being present in two paragraphs instead of one. Correction is required. See MPEP § 608.01(b).

Priority / Continuity

5) This application is a Continuation application of SN 10/170,638, filed 06/14/02, *now U.S. patent 6,723,328*, which is a Continuation application of SN 09/592,417, filed 06/13/2000, *now U.S. patent 6,428,789*, which is a Divisional of application SN 08/483,345, filed 06/07/1995, *now U.S. patent 6,132,733*, which is a Division application of SN 07/775,912, filed 10/15/1991, *now U.S. patent 5,453,273*, which is a Continuation of application SN 07/341,867, filed 04/21/1989, *now abandoned*.

Specification

6) The specification is objected to for the following reason:

The first paragraph of the specification does not accurately reflect the current issued status of one of the earlier applications as indicated above in italicized letters under the section 'Priority/Continuity'. Correction is requested.

Double Patenting Rejection(s)

7) The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R. 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. 3.73(b).

8) Claims 1-4 are rejected under the judicially created doctrine of obviousness-type double patenting over claims 5 and 11 of the US patent 6,132,733 ('733). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 5 and 11 of the '733 patent are drawn to a ringworm vaccine comprising a carrier and an effective amount of a homogenized, killed pure culture comprising *Microsporum canis*, *Microsporum gypsum* and

Trichophyton mentagrophytes, wherein the culture is filtered, and therefore anticipate the instant claims.

9) Claims 1-4 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of the US patent US 5,453,273 ('273) in view of Krueger AP (Patent 2,011,225 – Applicants' IDS).

Claims 1-4 of the '273 patent disclosed a ringworm vaccine comprising a carrier and an effective amount of a homogenized, formaldehyde-killed pure culture comprising *Microsporum canis*, *Microsporum gypsum*, and *Trichophyton mentagrophytes*. The ringworm vaccine of the '273 patent differs from the instantly claimed ringworm vaccine in that it fails to expressly state that the culture is filtered, or isolated by filtration.

However, isolating a fungal culture via the use of a filter was conventional and routinely practiced in the art of Mycology or of microbial vaccines. For instance, Krueger in 1935 taught the use of filtration to isolate the culture or cell components during the preparation of a fungal vaccine in order to separate the broken fungi, such as, *Tinea trychophytina*, from unbroken ones. See Example 5; and claims 7 and 11.

Therefore, it would have been *prima facie* obvious to one of skill in the art to isolate the dermatophyte cultures, *Microsporum canis*, *Microsporum gypsum* and *Trichophyton mentagrophytes*, of the '273 patent using Krueger's filtration to produce the instant invention, with a reasonable expectation of success. Given Krueger's showing that isolation by filtration has been a routine step used since 1935 in the making a prophylactic fungal antigen (i.e., vaccine), one of ordinary skill in the art would have been motivated to use Krueger's isolation by filtration for the expected benefit of separating the undesired cell components as taught by Krueger.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

10) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

11) Claims 1-4 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 1 is vague and indefinite in the limitation: 'effective amount' because it is

unclear what amount is encompassed in this limitation. The term 'effective' is a relative term which is not specifically defined by the claim. The specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the claim. What amount qualifies as an 'effective' amount, and in what capacity the amount is 'effective', i.e., prophylactically effective, therapeutically effective etc., is unclear.

(b) Claims 2-4 are indefinite, confusing, and have improper antecedent basis in the limitation: 'the dermatophytes'. Claims 2-4 depend from claim 1, which does not include the generic limitation of a 'dermatophyte'.

(c) Claims 2-4, which depend from claim 1, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

Remarks

12) Claims 1-4 stand rejected.

13) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax number (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

14) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

15) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

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July 2006

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

July, 2006



S. DEVI, PH.D.
PRIMARY EXAMINER